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**Anh Nguyen**
05/05/04 12:28 PM

To: NCIC HPV@EPA
cc:
Subject: Fw: Environmental Defense comments on the Reclaimed Substances Category

----- Forwarded by Anh Nguyen/DC/USEPA/US on 05/05/2004 12:28 PM -----

**rdenison@environmentaldefense.org**
05/05/2004 12:00 PM

To: NCIC OPPT@EPA, ChemRTK HPV@EPA, Rtk Chem@EPA, Karen Boswell/DC/USEPA/US@EPA, Grayt@api.org
cc: MTC@mchsi.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org
Subject: Environmental Defense comments on the Reclaimed Substances Category

(Submitted via Internet 5/5/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and Grayt@api.org)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for the Reclaimed Substances Category.

The Petroleum HPV Testing Group of the American Petroleum Institute, in response to EPA's High Production Volume (HPV) Chemical Challenge, has submitted robust summaries and a test plan describing available data and proposing additional studies for the reclaimed substances category. This is a complex category that includes a number of petroleum streams containing naphthenic acids, phenolics, disulfides, acids and/or caustics. According to the test plan, each of these is an intermediate stream, fraction or by-product that results from refining of petroleum products. Most of these mixtures are processed using caustic sodium hydroxide solutions to remove sulfur impurities. As such, this category is composed of approximately a dozen complex mixtures of organic chemicals and each mixture has its own CAS number. The complexity of these mixtures is further confounded by the fact that the individual mixtures may vary significantly from one refinery to another and even with the source of the petroleum refined in the same refinery. Thus, the exact composition of any one of the dozen mixtures in this category is unknown.

Given the complexity of the category, we appreciate that it is not possible to provide precise data for the chemical/physical properties and environmental fate that address all of its members. However, data for their ecotoxicity and mammalian toxicity are quite limited. In some cases some lesser need for data appears to be acceptable, while in other cases a good deal more characterization appears to be needed.

According to this submission, most of the individual mixtures addressed in this category are reclaimed and used in other processes, frequently in closed systems. The sponsor claims they are not released, transported or used in such a manner that might present a threat to human or environmental health. Therefore, the sponsor proposes that the SIDS elements required for other HPV chemicals not be addressed for each of these mixtures. They propose instead that the focus should be limited to a single mixture, naphthenic acids.
Whereas some data to address the required SIDS elements are available for naphthenic acids, it appears little or no data are available for most other members of this category.

TSCA or its associated regulations provide exemptions for certain materials that are not isolated, never produced for commercial purposes, etc. To the extent that these exemptions apply to members of this category, the sponsor is free to make that case. However, for those not meeting such criteria, data need to be provided. And especially if these chemical mixtures or their residues have the potential to cause exposure or be released into the environment (e.g., those materials that are "disposed as waste" (CAS# 68815-21-4), "used for pH control" (CAS# 64742-24-1) or whose fate is otherwise undefined (CAS# 64742-40-1)), a great deal more information should be generated and provided in order to assess risks they may pose to

environmental and human health.

We realize that these are complex mixtures the contents of which may vary significantly. If the other members of this category are so different from naphthenic acid, then they should be formed into a different chemical category or be evaluated individually, and naphthenic acids should also be considered independently.

According to the test plan, naphthenic acids occur naturally in petroleum and consist primarily of alkyl-substituted cycloaliphatic carboxylic acids, with smaller amounts of acyclic aliphatic acids. Naphthenic acids are said to be the only materials in this category sold commercially, and are reported to be used primarily in industrial applications as oil-soluble metal soaps, wood preservatives and corrosion inhibitors. The test plan provides no information regarding their transport, possible sources of release into the environment or potential risks their use may pose to human and environmental health.

Data developed for naphthenic acids suggest that this mixture is relatively non-toxic to mammals on acute administration. However, they are toxic at relatively low doses in repeat dose studies and reproductive/developmental studies and they are found to be carcinogenic in chronic studies. According to the test plan, the data from the repeat dose studies and reproductive/ developmental studies "are not of sufficient quality to adequately address these endpoints" and the test plan proposes that additional studies be conducted. Whereas we are often pleased to see sponsors proposed to develop needed additional data, we would point out in the present case that the study indicating naphthenic acids are toxic on repeated dosing is described in a recent (2003) peer-reviewed paper published in the open literature. The data on reproductive/developmental effects are described on the EPA website and should thus be available to the EPA. The study indicating naphthenic acids may be carcinogenic was conducted by the National Toxicology Program and, as such, all the details of that study, including the repeated dose studies done prior to the chronic study, are available to the public. Thus, we would recommend a careful assessment of available data prior to having these studies repeated. That is, repeating animal toxicity studies of naphthenic acids without careful assessment of currently available data will require considerable additional time and sacrifice of animals, and could either duplicate existing data, or yield results that would only further confound the issue and thus require still more studies and time.

In summary, due to the number of complex mixtures addressed, this is a very complex test plan. It is supported by well-organized robust summaries for naphthenic acids; however, data for other members of the category are largely lacking. This submission proposes that only data developed for naphthenic acids should be considered in assessing risks for petroleum streams in this category, because they are the only commercial products in the category. The test plan reasons that because the other category members are not commercial products or are caustic, e.g. phenols (CAS# 64743-3-9), the numerous other mixtures addressed in this category should not be subject to HPV requirements. We do not agree with this argument. That is, whereas we agree that any mixture that is documented to meet existing TSCA exemptions need not meet HPV requirements, we think any other mixture should meet reasonable HPV requirements. Testing for some of these streams may be limited to less than the full set of requirements, i.e., we see no reason to test highly caustic materials in animals, but in general they should be tested or their properties modeled as appropriate. And finally, data currently available for naphthenic acids should be carefully analyzed prior to the design and conduct of additional animal studies.

Thank you for this opportunity to comment.

Hazel B. Matthews, Ph.D.
Consulting Toxicologist, Environmental Defense

Richard Denison, Ph.D.
Senior Scientist, Environmental Defense